

Remarks

Restriction

Applicants have been required to elect one of the following inventions:

- I. Claims 1-21 (glucose biosensor).
- II. Claims 22-42 (method for glucose detection).
- III. Claims 43-77 (composition).

Applicants elect Claim Group III (Claims 43-77) without traverse.

Election of Species

The Examiner has also stated in section 6 of the Restriction/Election Requirement that “Claims 1, 2, and 16-21 are generic” and has required election of a single species. Although Claims 1, 2, and 16-21 are all in Claim Group I, based on a telephone conversation between Examiner Yang and Applicants’ undersigned representative on March 5, 2007, it is Applicants’ understanding that the requirement for election-of-species also applies to Claim Group III. Applicants respectfully request that Examiner Yang confirm this understanding in the next Office Action.

In accordance with Applicants’ understanding of the requirement for election-of-species, Applicants elect with traverse “three amino acid substitutions” (i.e., claims 64-70 and new claims 80-81) and the following triple amino acid substitution: a cysteine at position 149, an arginine at position 213 and a serine at position 238. Claims 64-70 and 80-81 read on the elected species.

Applicants traverse the election-of-species requirement because the instant application is a continuation-in-part (CIP) of granted U.S. Patent No. 6,855,556, which includes claims to glucose biosensors that recite in Markush form many of the same mutated glucose/galactose binding proteins that are recited in pending composition claims 43-83. For example, Claim 1 of the ‘556 patent recites “at least **one** amino acid substitution” in Markush form:

1. A glucose biosensor comprising at least one mutated glucose/galactose binding protein and at least one reporter group attached to said binding protein, such that said reporter group provides a detectable and reversible signal change when said mutated binding protein is exposed to varying glucose concentrations; wherein said at least one mutated glucose/galactose binding protein comprises **at least one amino acid substitution** selected from the group consisting of a cysteine at position 11, a cysteine at position 14, a cysteine at position 19, a cysteine at position 43, a cysteine at position 74, a cysteine at position 107, a

cysteine at position 110, a cysteine at position 112, a cysteine at position 113, a cysteine at position 137, a cysteine at position 149, a cysteine at position 213, a cysteine at position 216, a cysteine at position 238, a cysteine at position 287, and a cysteine at position 292, and wherein said detectable and reversible signal change is related to said varying concentrations.

Claim 43 of the instant CIP application recites in Markush form all of the single amino acid substitutions recited in Claim 1 of the issued parent¹.

Similarly, Claim 8 of the '556 parent patent recites "at least **two** amino acid substitutions" in Markush form:

8. A glucose biosensor comprising at least one mutated glucose/galactose binding protein and at least one reporter group attached to said binding protein, such that said reporter group provides a detectable and reversible signal change when said mutated binding protein is exposed to varying glucose concentrations; wherein said at least one mutated glucose/galactose binding protein comprises at least two amino acid substitutions, said at least **two** amino acid substitutions being selected from the group consisting of a cysteine at position 112 and a serine at position 238, a cysteine at position 149 and a serine at position 238, a cysteine at position 152 and a cysteine at position 182, a cysteine at position 152 and a serine at position 213, a cysteine at position 213 and a cysteine at position 238, a cysteine at position 149 and an arginine at position 213; and wherein said detectable and reversible signal change is related to said varying concentrations.

Claim 57 of the instant CIP application recites in Markush form all but one of the double amino acid substitutions recited in Claim 8 of the issued parent².

Likewise, Claim 15 of the '556 parent patent recites "at least **three** amino acid substitutions" in Markush form:

15. A glucose biosensor comprising at least one mutated glucose/galactose binding protein and at least one reporter group attached to said binding protein, such that said reporter group provides a detectable and reversible signal change when said mutated binding protein is exposed to varying glucose concentrations;

¹ Claim 43 of the instant application additionally recites in Markush form the following single amino acid substitutions not recited in Claim 1 of the '556 patent: a cysteine at position 1, a serine at position 1, a cysteine at position 236, and a cysteine at position 296. Claim 50 of the instant application additionally recites in Markush form a cysteine at position 152 and a cysteine at position 182.

² Claim 57 of the instant application additionally recites in Markush form the following double amino acid substitutions not recited in Claim 8 of the '556 patent: a cysteine at position 149 and a cysteine at position 213, a cysteine at position 149 and a threonine at position 213, a cysteine at position 149 and a leucine at position 213, a cysteine at position 149 and a tyrosine at position 213, a cysteine at position 149 and a serine at position 213, a cysteine at position 149 and an asparagine at position 223, a cysteine at position 149 and a cysteine at position 238, a cysteine at position 149 and a serine at position 256, a cysteine at position 149 and an arginine at position 256, a cysteine at position 152 and an arginine at position 213, a cysteine at position 152 and an asparagine at position 223, a cysteine at position 213 and a cysteine at position 255.

wherein said at least one mutated glucose/galactose binding protein comprises at least three amino acid substitutions, said at least **three** amino acid substitutions being selected from the group consisting of a cysteine at position 149 and a serine at position 213 and a serine at position 238, and a cysteine at position 149 and an arginine at position 213 and a serine at position 238; and wherein said detectable and reversible signal change is related to said varying concentrations.

Claim 64 of the instant CIP application recites both of the triple amino acid substitutions recited in Markush form in Claim 15 of the issued parent³.

Applicants respectfully submit that an examination of all of the recited species, or at least all of the species that are recited in the issued claims of the '556 parent patent, would not be unduly burdensome on the examiner in the instant CIP application. Many of the species recited in the pending claims have already been searched and examined in the parent, and the Office has concluded that they are novel and nonobvious in the context of the claimed glucose biosensors. It thus follows that examining claims to compositions comprising these same mutant binding proteins will not present a serious burden. To require otherwise would be inconsistent with the manner in which the Office handled the parent '556 patent.

Non-elected Claims 1-42 (i.e., the claims of groups I and II) have been canceled. New claims 78-83 have been added. The new claims are supported by the originally filed specification, including Examples 6-8. No new matter has been added.

Applicants expressly reserve the right to the non-elected subject matter including the right to file one or more continuation and/or divisional applications. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Applicant's undersigned attorney at the telephone number shown below.

³ Claim 64 of the instant application additionally recites in Markush form the following triple amino acid substitutions not recited in Claim 15 of the '556 patent: a cysteine at position 149, a cysteine at position 213 and a cysteine at position 238; a cysteine at position 149, a serine at position 213 and an asparagine at position 223; a cysteine at position 149, an asparagine at position 223 and an arginine at position 256; a cysteine at position 149, an arginine at position 213 and a cysteine at position 238; and a cysteine at position 149, a cysteine at position 213 and a serine at position 238.

Respectfully submitted,

/J. Timothy Meigs/

J. Timothy Meigs
Attorney for Applicant
Registration No. 38,241
(919) 597-6276

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417